



## Senate

General Assembly

**File No. 247**

February Session, 2010

Substitute Senate Bill No. 260

*Senate, April 1, 2010*

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

**AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR  
ROUTINE PATIENT CARE COSTS FOR CERTAIN CLINICAL TRIAL  
PATIENTS.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Section 38a-504a of the general statutes is repealed and  
2 the following is substituted in lieu thereof (*Effective January 1, 2011*):

3 Each individual health insurance policy providing coverage of the  
4 type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-  
5 469 delivered, issued for delivery, [or] renewed, amended or continued  
6 in this state, [on or after January 1, 2002,] shall provide coverage for the  
7 routine patient care costs, as defined in section 38a-504d, as amended  
8 by this act, associated with [cancer] clinical trials, in accordance with  
9 sections 38a-504b to 38a-504g, inclusive, as amended by this act. As  
10 used in this section and sections 38a-504b to 38a-504g, inclusive, as  
11 amended by this act, ["cancer clinical"] "clinical" trial" means an  
12 organized, systematic, scientific study of therapies, tests or other  
13 clinical interventions for purposes of treatment or palliation or

14 therapeutic intervention for the prevention of cancer, Parkinson's  
15 disease or multiple sclerosis in human beings. [, except that a clinical  
16 trial for the prevention of cancer is eligible for coverage only if it  
17 involves a therapeutic intervention and is a phase III clinical trial  
18 approved by one of the entities identified in section 38a-504b and is  
19 conducted at multiple institutions.]

20 Sec. 2. Section 38a-504b of the general statutes is repealed and the  
21 following is substituted in lieu thereof (*Effective January 1, 2011*):

22 (a) A clinical trial for the prevention of cancer, Parkinson's disease  
23 or multiple sclerosis shall be eligible for coverage of routine patient  
24 care costs only if it involves a therapeutic intervention, is a phase III  
25 clinical trial approved or qualified by one of the entities identified in  
26 subsection (b) of this section and is conducted at multiple institutions.

27 (b) In order to be eligible for coverage of routine patient care costs,  
28 as defined in section 38a-504d, as amended by this act, a [cancer]  
29 clinical trial shall be (1) conducted under the auspices of an  
30 independent peer-reviewed protocol that has been reviewed and  
31 approved by: [(1)] (A) One of the National Institutes of Health; [or (2)]  
32 (B) a National Cancer Institute affiliated cooperative group; [or (3)] (C)  
33 the federal Food and Drug Administration as part of an investigational  
34 new drug or device exemption; or [(4)] (D) the federal Department of  
35 Defense or Veterans Affairs; or (2) qualified to receive Medicare  
36 coverage of its routine patient care costs under the Medicare Clinical  
37 Trial Policy established under the September 19, 2000, Medicare  
38 National Coverage Determination, as amended from time to time.  
39 Nothing in sections 38a-504a to 38a-504g, inclusive, as amended by this  
40 act, shall be construed to require coverage for any single institution  
41 [cancer] clinical trial conducted solely under the approval of the  
42 institutional review board of an institution, or any trial that is no  
43 longer approved by an entity identified in [subdivision (1), (2), (3) or  
44 (4) of this section] subparagraph (A), (B), (C) or (D) of subdivision (1)  
45 of this subsection.

46 Sec. 3. Section 38a-504c of the general statutes is repealed and the

47 following is substituted in lieu thereof (*Effective January 1, 2011*):

48 In order to be eligible for coverage of routine patient care costs, as  
49 defined in section 38a-504d, as amended by this act, the insurer, health  
50 care center or plan administrator may require that the person or entity  
51 seeking coverage for the [cancer] clinical trial provide: (1) Evidence  
52 satisfactory to the insurer, health care center or plan administrator that  
53 the insured person receiving coverage meets all of the patient selection  
54 criteria for the [cancer] clinical trial, including credible evidence in the  
55 form of clinical or preclinical data showing that the [cancer] clinical  
56 trial is likely to have a benefit for the insured person that is  
57 commensurate with the risks of participation in the [cancer] clinical  
58 trial to treat the person's condition; [and] (2) evidence that the  
59 appropriate informed consent has been received from the insured  
60 person; [and] (3) copies of any medical records, protocols, test results  
61 or other clinical information used by the physician or institution  
62 seeking to enroll the insured person in the [cancer] clinical trial; [and]  
63 (4) a summary of the anticipated routine patient care costs in excess of  
64 the costs for standard treatment; [and] (5) information from the  
65 physician or institution seeking to enroll the insured person in the  
66 clinical trial regarding those items, including any routine patient care  
67 costs, that are eligible for reimbursement by an entity other than the  
68 insurer or health care center, including the entity sponsoring the  
69 clinical trial; and (6) any additional information that may be  
70 reasonably required for the review of a request for coverage of the  
71 [cancer] clinical trial. The health plan or insurer shall request any  
72 additional information about a [cancer] clinical trial [within] not later  
73 than five business days [of] after receiving a request for coverage from  
74 an insured person or a physician seeking to enroll an insured person in  
75 a [cancer] clinical trial. Nothing in sections 38a-504a to 38a-504g,  
76 inclusive, as amended by this act, shall be construed to require the  
77 insurer or health care center to provide coverage for routine patient  
78 care costs that are eligible for reimbursement by an entity other than  
79 the insurer, including the entity sponsoring the [cancer] clinical trial.

80 Sec. 4. Section 38a-504d of the general statutes is repealed and the

81 following is substituted in lieu thereof (*Effective January 1, 2011*):

82 (a) For purposes of sections 38a-504a to 38a-504g, inclusive, as  
83 amended by this act, "routine patient care costs" means: (1) [Coverage  
84 for medically] Medically necessary health care services that are  
85 incurred as a result of the treatment being provided to the insured  
86 person for purposes of the [cancer] clinical trial that would otherwise  
87 be covered if such services were not rendered pursuant to a [cancer]  
88 clinical trial. Such services shall include those rendered by a physician,  
89 diagnostic or laboratory tests, hospitalization or other services  
90 provided to the [patient] insured person during the course of  
91 treatment in the [cancer] clinical trial for a condition, or one of its  
92 complications, that is consistent with the usual and customary  
93 standard of care and would be covered if the insured person were not  
94 enrolled in a [cancer] clinical trial. Such hospitalization shall include  
95 treatment at an out-of-network facility if such treatment is not  
96 available in-network and not eligible for reimbursement by the  
97 sponsors of such clinical trial, [;] and (2) [coverage for routine patient  
98 care] costs incurred for drugs provided to the insured person, in  
99 accordance with section [38a-518b] 38a-492b, as amended by this act,  
100 provided such drugs have been approved for sale by the federal Food  
101 and Drug Administration.

102 (b) Routine patient care costs shall be subject to the terms,  
103 conditions, restrictions, exclusions and limitations of the contract or  
104 certificate of insurance between the subscriber and the insurer or  
105 health plan, including limitations on out-of-network care, except that  
106 treatment at an out-of-network hospital as provided in subdivision (1)  
107 of subsection (a) of this section shall be made available by the out-of-  
108 network hospital and the insurer or health care center at no greater  
109 cost to the insured person than if such treatment was available in-  
110 network. The insurer or health care center may require that any  
111 routine tests or services required under the [cancer] clinical trial  
112 protocol be performed by providers or institutions under contract with  
113 the insurer or health care center.

114 (c) Notwithstanding the provisions of subsection (a) of this section,  
115 routine patient care costs shall not include: (1) The cost of an  
116 investigational new drug or device that has not been approved for  
117 market for any indication by the federal Food and Drug  
118 Administration; (2) the cost of a non-health-care service that an insured  
119 person may be required to receive as a result of the treatment being  
120 provided for the purposes of the [cancer] clinical trial; (3) facility,  
121 ancillary, professional services and drug costs that are paid for by  
122 grants or funding for the [cancer] clinical trial; (4) costs of services that  
123 (A) are inconsistent with widely accepted and established regional or  
124 national standards of care for a particular diagnosis, or (B) are  
125 performed specifically to meet the requirements of the [cancer] clinical  
126 trial; (5) costs that would not be covered under the insured person's  
127 policy for noninvestigational treatments, including, but not limited to,  
128 items excluded from coverage under the insured person's contract  
129 with the insurer or health plan; and (6) transportation, lodging, food or  
130 any other expenses associated with travel to or from a facility  
131 providing the [cancer] clinical trial, for the insured person or any  
132 family member or companion.

133 Sec. 5. Section 38a-504e of the general statutes is repealed and the  
134 following is substituted in lieu thereof (*Effective January 1, 2011*):

135 (a) Providers, hospitals and institutions that provide routine patient  
136 care services as set forth in subsection (a) of section 38a-504d, as  
137 amended by this act, as part of a [cancer] clinical trial that meets the  
138 requirements of sections 38a-504a to 38a-504g, inclusive, as amended  
139 by this act, and is approved for coverage by the insurer or health care  
140 center shall not bill the insurer or health care center or the insured  
141 person for any facility, ancillary or professional services or costs that  
142 are not routine patient care services as set forth in subsection (a) of  
143 section 38a-504d, as amended by this act, or for any product or service  
144 that is paid by the entity sponsoring or funding the [cancer] clinical  
145 trial.

146 (b) Providers, hospitals, institutions and insured persons may

147 appeal a health plan's denials of payment for services only to the  
148 extent permitted by the contract between the insurer or health care  
149 center and the provider, hospital or institution.

150 (c) Providers, hospitals or institutions that have contracts with the  
151 insurer or health care center to render covered routine patient care  
152 services to insured persons as part of a [cancer] clinical trial [may] shall  
153 not bill the insured person for the cost of any covered routine patient  
154 care service.

155 (d) Providers, hospitals or institutions that do not have a contract  
156 with the insurer or health care center to render covered routine patient  
157 care services to insured persons as part of a [cancer] clinical trial [may]  
158 shall not bill the insured person for the cost of any covered routine  
159 patient care service.

160 (e) Nothing in this section shall be construed to prohibit a provider,  
161 hospital or institution from collecting a deductible or copayment as set  
162 forth in the insured person's contract for any covered routine patient  
163 care service.

164 (f) Pursuant to subsection (b) of section 38a-504d, as amended by  
165 this act, insurers or health care centers shall be required to pay  
166 providers, hospitals and institutions that do not have a contract with  
167 the insurer or health care center to render covered routine patient care  
168 services to insured persons the lesser of (1) the lowest contracted per  
169 diem, fee schedule rate or case rate that the insurer or health care  
170 center pays to any participating provider in the state of Connecticut for  
171 similar in-network services, or (2) the billed charges. Providers,  
172 hospitals or institutions [may] shall not collect any amount more than  
173 the total amount paid by the insurer or health care center and the  
174 insured person in the form of a deductible or copayment set forth in  
175 the insured person's contract. Such amount shall be deemed by the  
176 provider, hospital or institution to be payment in full.

177 Sec. 6. Section 38a-504f of the general statutes is repealed and the  
178 following is substituted in lieu thereof (*Effective January 1, 2011*):

179 (a) (1) For purposes of cancer clinical trials, the Insurance  
180 Department, in cooperation with the Connecticut Oncology  
181 Association, the American Cancer Society, the Connecticut Association  
182 of Health Plans and Anthem Blue Cross of Connecticut, shall develop a  
183 standardized form that all providers, hospitals and institutions shall  
184 submit to the insurer or health care center when seeking to enroll an  
185 insured person in a cancer clinical trial. An insurer or health care  
186 center [may] shall not substitute any other approval request form for  
187 the form developed by the department, except that any insurer or  
188 health care center that has entered into an agreement to provide  
189 coverage for cancer clinical trials approved pursuant to section 38a-  
190 504g, as amended by this act, may use the form or process established  
191 by such agreement.

192 (2) For purposes of Parkinson's disease or multiple sclerosis clinical  
193 trials, the Insurance Department, in cooperation with at least one state  
194 nonprofit Parkinson's disease or multiple sclerosis research or  
195 advocacy organization, as applicable, at least one national nonprofit  
196 Parkinson's disease or multiple sclerosis research or advocacy  
197 organization, as applicable, the Connecticut Association of Health  
198 Plans and Anthem Blue Cross of Connecticut, shall develop a  
199 standardized form that all providers, hospitals and institutions shall  
200 submit to the insurer or health care center when seeking to enroll an  
201 insured person in a Parkinson's disease or multiple sclerosis clinical  
202 trial. An insurer or health care center shall not substitute any other  
203 approval request form for the form developed by the department,  
204 except that any insurer or health care center that has entered into an  
205 agreement to provide coverage for clinical trials approved pursuant to  
206 section 38a-504g, as amended by this act, may use the form or process  
207 established by such agreement.

208 (b) Any insurer or health care center that receives the department  
209 form from a provider, hospital or institution seeking coverage for the  
210 routine patient care costs of an insured person in a [cancer] clinical  
211 trial shall approve or deny coverage for such services [within] not later  
212 than five business days [of] after receiving such request and any other

213 reasonable supporting materials requested by the insurer or health  
214 plan pursuant to section 38a-504c, as amended by this act, except that  
215 an insurer or health care center that utilizes independent experts to  
216 review such requests shall respond [within] not later than ten business  
217 days after receiving such request and supporting materials. Requests  
218 for coverage of phase III clinical trials for the prevention of cancer,  
219 Parkinson's disease or multiple sclerosis pursuant to section [38a-504a]  
220 38a-504b, as amended by this act, shall be approved or denied [within]  
221 not later than fourteen business days after receiving such request and  
222 supporting materials.

223 (c) The insured, or the provider with the insured's written consent,  
224 may appeal any denial of coverage for medical necessity to an external,  
225 independent review pursuant to section 38a-478n. Such external  
226 review shall be conducted by a properly qualified review agent whom  
227 the department has determined does not have a conflict of interest  
228 regarding the [cancer] clinical trial.

229 (d) The Insurance Commissioner shall adopt regulations, in  
230 accordance with chapter 54, to implement the provisions of this  
231 section.

232 Sec. 7. Section 38a-504g of the general statutes is repealed and the  
233 following is substituted in lieu thereof (*Effective January 1, 2011*):

234 (a) Any insurer or health care center with coverage policies for care  
235 in [cancer] clinical trials shall submit such policies to the Insurance  
236 Department for evaluation and approval. The department shall certify  
237 whether the insurer's or health care center's coverage policy for routine  
238 patient care costs associated with [cancer] clinical trials is substantially  
239 equivalent to the requirements of sections 38a-504a to 38a-504g,  
240 inclusive, as amended by this act. If the department finds that such  
241 coverage is substantially equivalent to the requirements of sections  
242 38a-504a to 38a-504g, inclusive, as amended by this act, the insurer or  
243 health care center shall be exempt from the provisions of sections 38a-  
244 504a to 38a-504g, inclusive, as amended by this act.



245 (b) Any such insurer or health care center shall report annually, in  
246 writing, to the department that there have been no changes in the  
247 policy as certified by the department. If there has been any change in  
248 the policy, the insurer or health care center shall resubmit its policy for  
249 certification by the department.

250 (c) Any insurer or health care center coverage policy found by the  
251 department not to be substantially equivalent to the requirements of  
252 sections 38a-504a to 38a-504g, inclusive, as amended by this act, shall  
253 abide by the requirements of sections 38a-504a to 38a-504g, inclusive,  
254 as amended by this act, until the insurer or health care center has  
255 received such certification by the department.

256 Sec. 8. Section 38a-542a of the general statutes is repealed and the  
257 following is substituted in lieu thereof (*Effective January 1, 2011*):

258 Each group health insurance policy providing coverage of the type  
259 specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469  
260 delivered, issued for delivery, [or] renewed, amended or continued in  
261 this state, [on or after January 1, 2002,] shall provide coverage for the  
262 routine patient care costs, as defined in section 38a-542d, as amended  
263 by this act, associated with [cancer] clinical trials, in accordance with  
264 sections 38a-542b to 38a-542g, inclusive, as amended by this act. As  
265 used in this section and sections 38a-542b to 38a-542g, inclusive, as  
266 amended by this act, ["cancer clinical"] "clinical trial" means an  
267 organized, systematic, scientific study of therapies, tests or other  
268 clinical interventions for purposes of treatment or palliation or  
269 therapeutic intervention for the prevention of cancer, Parkinson's  
270 disease or multiple sclerosis in human beings. [, except that a clinical  
271 trial for the prevention of cancer is eligible for coverage only if it  
272 involves a therapeutic intervention and is a phase III clinical trial  
273 approved by one of the entities identified in section 38a-542b and is  
274 conducted at multiple institutions.]

275 Sec. 9. Section 38a-542b of the general statutes is repealed and the  
276 following is substituted in lieu thereof (*Effective January 1, 2011*):

277     (a) A clinical trial for the prevention of cancer, Parkinson's disease  
278 or multiple sclerosis shall be eligible for coverage of routine patient  
279 care costs only if it involves a therapeutic intervention, is a phase III  
280 clinical trial approved or qualified by one of the entities identified in  
281 subsection (b) of this section and is conducted at multiple institutions.

282     (b) In order to be eligible for coverage of routine patient care costs,  
283 as defined in section 38a-542d, as amended by this act, a [cancer]  
284 clinical trial shall be (1) conducted under the auspices of an  
285 independent peer-reviewed protocol that has been reviewed and  
286 approved by: [(1)] (A) One of the National Institutes of Health; [or (2)]  
287 (B) a National Cancer Institute affiliated cooperative group; [or (3)] (C)  
288 the federal Food and Drug Administration as part of an investigational  
289 new drug or device exemption; or [(4)] (D) the federal Department of  
290 Defense or Veterans Affairs; or (2) qualified to receive Medicare  
291 coverage of its routine patient care costs under the Medicare Clinical  
292 Trial Policy established under the September 19, 2000, Medicare  
293 National Coverage Determination, as amended from time to time.  
294 Nothing in sections 38a-542a to 38a-542g, inclusive, as amended by this  
295 act, shall be construed to require coverage for any single institution  
296 [cancer] clinical trial conducted solely under the approval of the  
297 institutional review board of an institution, or any trial that is no  
298 longer approved by an entity identified in [subdivision (1), (2), (3) or  
299 (4) of this section] subparagraph (A), (B), (C) or (D) of subdivision (1)  
300 of this subsection.

301     Sec. 10. Section 38a-542c of the general statutes is repealed and the  
302 following is substituted in lieu thereof (*Effective January 1, 2011*):

303     In order to be eligible for coverage of routine patient care costs, as  
304 defined in section 38a-542d, as amended by this act, the insurer, health  
305 care center or plan administrator may require that the person or entity  
306 seeking coverage for the [cancer] clinical trial provide: (1) Evidence  
307 satisfactory to the insurer, health care center or plan administrator that  
308 the insured person receiving coverage meets all of the patient selection  
309 criteria for the [cancer] clinical trial, including credible evidence in the

310 form of clinical or pre-clinical data showing that the [cancer] clinical  
311 trial is likely to have a benefit for the insured person that is  
312 commensurate with the risks of participation in the [cancer] clinical  
313 trial to treat the person's condition; [and] (2) evidence that the  
314 appropriate informed consent has been received from the insured  
315 person; [and] (3) copies of any medical records, protocols, test results  
316 or other clinical information used by the physician or institution  
317 seeking to enroll the insured person in the [cancer] clinical trial; [and]  
318 (4) a summary of the anticipated routine patient care costs in excess of  
319 the costs for standard treatment; [and] (5) information from the  
320 physician or institution seeking to enroll the insured person in the  
321 clinical trial regarding those items, including any routine patient care  
322 costs, that are eligible for reimbursement by an entity other than the  
323 insurer or health care center, including the entity sponsoring the  
324 clinical trial; and (6) any additional information that may be  
325 reasonably required for the review of a request for coverage of the  
326 [cancer] clinical trial. The health plan or insurer shall request any  
327 additional information about a [cancer] clinical trial [within] not later  
328 than five business days [of] after receiving a request for coverage from  
329 an insured person or a physician seeking to enroll an insured person in  
330 a [cancer] clinical trial. Nothing in sections 38a-542a to 38a-542g,  
331 inclusive, as amended by this act, shall be construed to require the  
332 insurer or health care center to provide coverage for routine patient  
333 care costs that are eligible for reimbursement by an entity other than  
334 the insurer, including the entity sponsoring the [cancer] clinical trial.

335 Sec. 11. Section 38a-542d of the general statutes is repealed and the  
336 following is substituted in lieu thereof (*Effective January 1, 2011*):

337 (a) For purposes of sections 38a-542a to 38a-542g, inclusive, as  
338 amended by this act, "routine patient care costs" means: (1) [Coverage  
339 for medically] Medically necessary health care services that are  
340 incurred as a result of the treatment being provided to the insured  
341 person for purposes of the [cancer] clinical trial that would otherwise  
342 be covered if such services were not rendered pursuant to a [cancer]  
343 clinical trial. Such services shall include those rendered by a physician,

344 diagnostic or laboratory tests, hospitalization or other services  
345 provided to the [patient] insured person during the course of  
346 treatment in the [cancer] clinical trial for a condition, or one of its  
347 complications, that is consistent with the usual and customary  
348 standard of care and would be covered if the insured person were not  
349 enrolled in a [cancer] clinical trial. Such hospitalization shall include  
350 treatment at an out-of-network facility if such treatment is not  
351 available in-network and not eligible for reimbursement by the  
352 sponsors of such clinical trial; and (2) [coverage for routine patient  
353 care] costs incurred for drugs provided to the insured person, in  
354 accordance with section 38a-518b, as amended by this act, provided  
355 such drugs have been approved for sale by the federal Food and Drug  
356 Administration.

357 (b) Routine patient care costs shall be subject to the terms,  
358 conditions, restrictions, exclusions and limitations of the contract or  
359 certificate of insurance between the subscriber and the insurer or  
360 health plan, including limitations on out-of-network care, except that  
361 treatment at an out-of-network hospital as provided in subdivision (1)  
362 of subsection (a) of this section shall be made available by the out-of-  
363 network hospital and the insurer or health care center at no greater  
364 cost to the insured person than if such treatment was available in-  
365 network. The insurer or health care center may require that any  
366 routine tests or services required under the [cancer] clinical trial  
367 protocol be performed by providers or institutions under contract with  
368 the insurer or health care center.

369 (c) Notwithstanding the provisions of subsection (a) of this section,  
370 routine patient care costs shall not include: (1) The cost of an  
371 investigational new drug or device that has not been approved for  
372 market for any indication by the federal Food and Drug  
373 Administration; (2) the cost of a non-health-care service that an insured  
374 person may be required to receive as a result of the treatment being  
375 provided for the purposes of the [cancer] clinical trial; (3) facility,  
376 ancillary, professional services and drug costs that are paid for by  
377 grants or funding for the [cancer] clinical trial; (4) costs of services that

378 (A) are inconsistent with widely accepted and established regional or  
379 national standards of care for a particular diagnosis, or (B) are  
380 performed specifically to meet the requirements of the [cancer] clinical  
381 trial; (5) costs that would not be covered under the insured person's  
382 policy for noninvestigational treatments, including, but not limited to,  
383 items excluded from coverage under the insured person's contract  
384 with the insurer or health plan; and (6) transportation, lodging, food or  
385 any other expenses associated with travel to or from a facility  
386 providing the [cancer] clinical trial, for the insured person or any  
387 family member or companion.

388 Sec. 12. Section 38a-542e of the general statutes is repealed and the  
389 following is substituted in lieu thereof (*Effective January 1, 2011*):

390 (a) Providers, hospitals and institutions that provide routine patient  
391 care services as set forth in subsection (a) of section 38a-542d, as  
392 amended by this act, as part of a [cancer] clinical trial that meets the  
393 requirements of sections 38a-542a to 38a-542g, inclusive, as amended  
394 by this act, and is approved for coverage by the insurer or health care  
395 center shall not bill the insurer or health care center or the insured  
396 person for any facility, ancillary or professional services or costs that  
397 are not routine patient care services as set forth in subsection (a) of  
398 section 38a-542d, as amended by this act, or for any product or service  
399 that is paid by the entity sponsoring or funding the [cancer] clinical  
400 trial.

401 (b) Providers, hospitals, institutions and insured persons may  
402 appeal a health plan's denials of payment for services only to the  
403 extent permitted by the contract between the insurer or health care  
404 center and the provider, hospital or institution.

405 (c) Providers, hospitals or institutions that have contracts with the  
406 insurer or health care center to render covered routine patient care  
407 services to insured persons as part of a [cancer] clinical trial [may] shall  
408 not bill the insured person for the cost of any covered routine patient  
409 care service.

410 (d) Providers, hospitals or institutions that do not have a contract  
411 with the insurer or health care center to render covered routine patient  
412 care services to insured persons as part of a [cancer] clinical trial [may]  
413 shall not bill the insured person for the cost of any covered routine  
414 patient care service.

415 (e) Nothing in this section shall be construed to prohibit a provider,  
416 hospital or institution from collecting a deductible or copayment as set  
417 forth in the insured person's contract for any covered routine patient  
418 care service.

419 (f) Pursuant to subsection (b) of section 38a-542d, as amended by  
420 this act, insurers or health care centers shall be required to pay  
421 providers, hospitals and institutions that do not have a contract with  
422 the insurer or health care center to render covered routine patient care  
423 services to insured persons the lesser of (1) the lowest contracted per  
424 diem, fee schedule rate or case rate that the insurer or health care  
425 center pays to any participating provider in the state of Connecticut for  
426 similar in-network services, or (2) the billed charges. Providers,  
427 hospitals or institutions [may] shall not collect any amount more than  
428 the total amount paid by the insurer or health care center and the  
429 insured person in the form of a deductible or copayment set forth in  
430 the insured person's contract. Such amount shall be deemed by the  
431 provider, hospital or institution to be payment in full.

432 Sec. 13. Section 38a-542f of the general statutes is repealed and the  
433 following is substituted in lieu thereof (*Effective January 1, 2011*):

434 (a) (1) For purposes of cancer clinical trials, the Insurance  
435 Department, in cooperation with the Connecticut Oncology  
436 Association, the American Cancer Society, the Connecticut Association  
437 of Health Plans and Anthem Blue Cross of Connecticut, shall develop a  
438 standardized form that all providers, hospitals and institutions shall  
439 submit to the insurer or health care center when seeking to enroll an  
440 insured person in a cancer clinical trial. An insurer or health care  
441 center [may] shall not substitute any other approval request form for  
442 the form developed by the department, except that any insurer or

443 health care center that has entered into an agreement to provide  
444 coverage for cancer clinical trials approved pursuant to section 38a-  
445 542g, as amended by this act, may use the form or process established  
446 by such agreement.

447 (2) For purposes of Parkinson's disease or multiple sclerosis clinical  
448 trials, the Insurance Department, in cooperation with at least one state  
449 nonprofit Parkinson's disease or multiple sclerosis research or  
450 advocacy organization, as applicable, at least one national nonprofit  
451 Parkinson's disease or multiple sclerosis research or advocacy  
452 organization, as applicable, the Connecticut Association of Health  
453 Plans and Anthem Blue Cross of Connecticut, shall develop a  
454 standardized form that all providers, hospitals and institutions shall  
455 submit to the insurer or health care center when seeking to enroll an  
456 insured person in a Parkinson's disease or multiple sclerosis clinical  
457 trial. An insurer or health care center shall not substitute any other  
458 approval request form for the form developed by the department,  
459 except that any insurer or health care center that has entered into an  
460 agreement to provide coverage for clinical trials approved pursuant to  
461 section 38a-504g, as amended by this act, may use the form or process  
462 established by such agreement.

463 (b) Any insurer or health care center that receives the department  
464 form from a provider, hospital or institution seeking coverage for the  
465 routine patient care costs of an insured person in a [cancer] clinical  
466 trial shall approve or deny coverage for such services [within] not later  
467 than five business days [of] after receiving such request and any other  
468 reasonable supporting materials requested by the insurer or health  
469 plan pursuant to section 38a-542c, as amended by this act, except that  
470 an insurer or health care center that utilizes independent experts to  
471 review such requests shall respond [within] not later than ten business  
472 days after receiving such request and supporting materials. Requests  
473 for coverage of phase III clinical trials for the prevention of cancer,  
474 Parkinson's disease or multiple sclerosis pursuant to section [38a-542a]  
475 38-542b, as amended by this act, shall be approved or denied [within]  
476 not later than fourteen business days after receiving such request and

477 supporting materials.

478 (c) The insured, or the provider with the insured's written consent,  
479 may appeal any denial of coverage for medical necessity to an external,  
480 independent review pursuant to section 38a-478n. Such external  
481 review shall be conducted by a properly qualified review agent whom  
482 the department has determined does not have a conflict of interest  
483 regarding the [cancer] clinical trial.

484 (d) The Insurance Commissioner shall adopt regulations, in  
485 accordance with chapter 54, to implement the provisions of this  
486 section.

487 Sec. 14. Section 38a-542g of the general statutes is repealed and the  
488 following is substituted in lieu thereof (*Effective January 1, 2011*):

489 (a) Any insurer or health care center with coverage policies for care  
490 in [cancer] clinical trials shall submit such policies to the Insurance  
491 Department for evaluation and approval. The department shall certify  
492 whether the insurer's or health care center's coverage policy for routine  
493 patient care costs associated with [cancer] clinical trials is substantially  
494 equivalent to the requirements of sections 38a-542a to 38a-542g,  
495 inclusive, as amended by this act. If the department finds that such  
496 coverage is substantially equivalent to the requirements of sections  
497 38a-542a to 38a-542g, inclusive, as amended by this act, the insurer or  
498 health care center shall be exempt from the provisions of sections 38a-  
499 542a to 38a-542g, inclusive, as amended by this act.

500 (b) Any such insurer or health care center shall report annually, in  
501 writing, to the department that there have been no changes in the  
502 policy as certified by the department. If there has been any change in  
503 the policy, the insurer or health care center shall resubmit its policy for  
504 certification by the department.

505 (c) Any insurer or health care center coverage policy found by the  
506 department not to be substantially equivalent to the requirements of  
507 sections 38a-542a to 38a-542g, inclusive, as amended by this act, shall



508 abide by the requirements of sections 38a-542a to 38a-542g, inclusive,  
509 as amended by this act, until the insurer or health care center has  
510 received such certification by the department.

511 Sec. 15. Section 38a-492b of the general statutes is repealed and the  
512 following is substituted in lieu thereof (*Effective January 1, 2011*):

513 (a) Each individual health insurance policy delivered, issued for  
514 delivery, [or] renewed, amended or continued in this state, [on or after  
515 October 1, 1994, which] that provides coverage for prescribed drugs  
516 approved by the federal Food and Drug Administration for treatment  
517 of certain types of cancer or for Parkinson's disease or multiple  
518 sclerosis shall not exclude coverage of any such drug on the basis that  
519 such drug has been prescribed for the treatment of a type of cancer or  
520 for Parkinson's disease or multiple sclerosis for which the drug has not  
521 been approved by the federal Food and Drug Administration,  
522 provided the drug is recognized for treatment of the specific type of  
523 cancer for which the drug has been prescribed or for Parkinson's  
524 disease or multiple sclerosis in one of the following established  
525 reference compendia: (1) The U.S. Pharmacopoeia Drug Information  
526 Guide for the Health Care Professional (USP DI); (2) The American  
527 Medical Association's Drug Evaluations (AMA DE); or (3) The  
528 American Society of Hospital Pharmacists' American Hospital  
529 Formulary Service Drug Information (AHFS-DI).

530 (b) Nothing in subsection (a) of this section shall be construed to  
531 require coverage for any experimental or investigational drugs or any  
532 drug which the federal Food and Drug Administration has determined  
533 to be contraindicated for treatment of the specific type of cancer for  
534 which the drug has been prescribed or for Parkinson's disease or  
535 multiple sclerosis.

536 (c) [Nothing] Except as specified, nothing in this section shall be  
537 construed to create, impair, limit or modify authority to provide  
538 reimbursement for drugs used in the treatment of any other disease or  
539 condition.

540 Sec. 16. Section 38a-518b of the general statutes is repealed and the  
 541 following is substituted in lieu thereof (*Effective January 1, 2011*):

542 (a) Each group health insurance policy delivered, issued for  
 543 delivery, [or] renewed, amended or continued in this state, [on or after  
 544 October 1, 1994, which] that provides coverage for prescribed drugs  
 545 approved by the federal Food and Drug Administration for treatment  
 546 of certain types of cancer or for Parkinson's disease or multiple  
 547 sclerosis shall not exclude coverage of any such drug on the basis that  
 548 such drug has been prescribed for the treatment of a type of cancer or  
 549 for Parkinson's disease or multiple sclerosis for which the drug has not  
 550 been approved by the federal Food and Drug Administration,  
 551 provided the drug is recognized for treatment of the specific type of  
 552 cancer for which the drug has been prescribed or for Parkinson's  
 553 disease or multiple sclerosis in one of the following established  
 554 reference compendia: (1) The U.S. Pharmacopoeia Drug Information  
 555 Guide for the Health Care Professional (USP DI); (2) The American  
 556 Medical Association's Drug Evaluations (AMA DE); or (3) The  
 557 American Society of Hospital Pharmacists' American Hospital  
 558 Formulary Service Drug Information (AHFS-DI).

559 (b) Nothing in subsection (a) of this section shall be construed to  
 560 require coverage for any experimental or investigational drugs or any  
 561 drug which the federal Food and Drug Administration has determined  
 562 to be contraindicated for treatment of the specific type of cancer for  
 563 which the drug has been prescribed or for Parkinson's disease or  
 564 multiple sclerosis.

565 (c) [Nothing] Except as specified, nothing in this section shall be  
 566 construed to create, impair, limit or modify authority to provide  
 567 reimbursement for drugs used in the treatment of any other disease or  
 568 condition.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>January 1, 2011</i>	38a-504a

Sec. 2	January 1, 2011	38a-504b
Sec. 3	January 1, 2011	38a-504c
Sec. 4	January 1, 2011	38a-504d
Sec. 5	January 1, 2011	38a-504e
Sec. 6	January 1, 2011	38a-504f
Sec. 7	January 1, 2011	38a-504g
Sec. 8	January 1, 2011	38a-542a
Sec. 9	January 1, 2011	38a-542b
Sec. 10	January 1, 2011	38a-542c
Sec. 11	January 1, 2011	38a-542d
Sec. 12	January 1, 2011	38a-542e
Sec. 13	January 1, 2011	38a-542f
Sec. 14	January 1, 2011	38a-542g
Sec. 15	January 1, 2011	38a-492b
Sec. 16	January 1, 2011	38a-518b

**Statement of Legislative Commissioners:**

In sections 2(a) and 9(a), "for the prevention of cancer, Parkinson's disease or multiple sclerosis" was inserted after "A clinical trial" for accuracy, and in sections 6(b) and 13(b), ", Parkinson's disease or multiple sclerosis" was inserted after "prevention of cancer" for internal consistency.

**INS**      *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

### **OFA Fiscal Note**

#### **State Impact:**

<b>Agency Affected</b>	<b>Fund-Effect</b>	<b>FY 11 \$</b>	<b>FY 12 \$</b>
State Comptroller - Fringe Benefits	GF & TF- Cost	Potential	Potential

Note: GF=General Fund; TF = Transportation Fund

#### **Municipal Impact:**

<b>Municipalities</b>	<b>Effect</b>	<b>FY 11 \$</b>	<b>FY 12 \$</b>
Various Municipalities	STATE MANDATE - Cost	Potential	Potential

### **Explanation**

The bill expands the mandated coverage of routine medical costs associated with cancer clinical trials and off-label cancer prescription drugs to include clinical trials for Parkinson's disease and multiple sclerosis and off-label prescription drugs. The potential cost to the state health plans cannot be determined as it is not known 1) whether the state's self-insured health plan will voluntarily adopt this mandate<sup>1</sup>; 2) how many state health plan participants diagnosed with multiple sclerosis or Parkinson's disease would choose to participate in a clinical trial; and 3) how much additional medical services would result from clinical trial participation.

According to the state's employee and retiree health plan subscriber

<sup>1</sup> Section 18 of P.A. 09-7 of the September Special Session required the Comptroller to convert the state employee health insurance plan to a self-insured arrangement for benefit periods on or after July 1, 2010. It is expected that this conversion will take place on schedule for July 1, 2010. Due to federal law, the state's FY 11 self-insured health plan would be exempt from state health insurance benefit mandates however in previous self-funded arrangements the state has traditionally adopted all state mandates.

agreement, services associated with or as follow-up to the use of any experimental or investigational treatment other than a peer-reviewed cancer clinical trial are not covered, unless approved by the plan provider on a case-by-case basis.

The bill may increase costs to certain fully insured municipal plans which do not provide the coverage specified by the bill. The coverage requirements may result in increased premium costs when municipalities enter into new contracts for health insurance on or after January 1, 2011. Due to federal law, municipalities with self-insured health plans are exempt from state health insurance benefit mandates.

### ***The Out Years***

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

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**OLR Bill Analysis****sSB 260*****AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CERTAIN CLINICAL TRIAL PATIENTS.*****SUMMARY:**

By law, individual and group health insurance policies and HMO contracts must cover (1) medically necessary hospitalization services and other routine patient care costs associated with cancer clinical trials and (2) off-label cancer prescription drugs. This bill expands the coverage requirements to include Parkinson's disease or multiple sclerosis (MS) clinical trials and off-label prescription drugs.

The bill applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; and (4) hospital or medical services, including coverage under an HMO plan. Due to federal law (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

EFFECTIVE DATE: January 1, 2011

**CLINICAL TRIALS**

The bill defines a "clinical trial" as an organized, systematic, scientific study of interventions for Parkinson's disease or MS treatment, palliation, or therapeutic invention for prevention. If the trial is for prevention, it must be a Phase III trial conducted at multiple institutions. (Phase III clinical trials compare a new drug or surgical procedure to the current standard of treatment.) This definition is already law with respect to cancer.

***Eligibility for Coverage***

By law, to be eligible for coverage, a cancer clinical trial must be conducted under an independent, peer-reviewed protocol approved by one of the National Institutes of Health, a National Cancer Institute-affiliated cooperative group, the Food and Drug Administration as part of an investigational new drug or device exemption, or the U. S. departments of Defense or Veterans' Affairs. The bill applies this requirement to clinical trials for Parkinson's disease or MS. It also makes eligible for coverage clinical trials for cancer, Parkinson's disease, or MS that are qualified to receive Medicare coverage under the Medicare Clinical Trials Policy established under the September 19, 2000 Medicare National Coverage Determination.

The insurer, HMO, or plan administrator may require the person or entity seeking coverage for the clinical trial to provide:

1. evidence that the patient meets all selection criteria for the clinical trial, including credible clinical evidence showing the clinical trial is likely to benefit the person compared to the risks of participation;
2. evidence that the patient has given his or her informed consent;
3. copies of medical records, protocols, test results, or other clinical information used to enroll the patient in the clinical trial;
4. a summary of the anticipated routine patient costs in excess of the standard treatment costs;
5. information regarding items that are eligible for reimbursement from other sources, including the entity sponsoring the clinical trial; and
6. additional information reasonably required to review the coverage request.

***Routine Patient Care Costs***

By law, "routine patient care costs" are (1) medically necessary

health care services, including physician services, diagnostic or laboratory tests, and hospitalization, incurred as a result of the treatment being provided that would otherwise be covered if they were not rendered as part of a clinical trial and (2) costs incurred for federal Food and Drug Administration (FDA) approved drugs. The services must be consistent with the usual and customary standard of care.

Hospitalization must include treatment at an out-of-network facility if such treatment is not available in-network and not eligible for reimbursement by the clinical trial.

Routine patient care costs must be subject to the terms, conditions, restrictions, exclusions, and limitations of the insurance contract or certificate, including limitations on out-of-network care. But treatment at an out-of-network hospital must be made available by the out-of-network hospital and the insurer or HMO at no greater cost to the insured person than if such treatment was available in-network. The insurer or HMO may require that any routine tests or services required under the clinical trial be performed by contracted providers.

Routine patient care costs do not include:

1. the cost of an investigational new drug or device that is not FDA approved;
2. the cost of a non-health-care service that an insured person may be required to receive as a result of the clinical trial;
3. facility, ancillary, professional services, and drug costs that are paid for by grants or funding for the clinical trial;
4. costs of services that (a) are inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis, or (b) are performed specifically to meet the requirements of the clinical trial;
5. costs that would not be covered under the insured person's



policy for noninvestigational treatments, including items excluded from coverage under the person's insurance contract; and

6. transportation, lodging, food, or any other expenses associated with travel to or from the clinical trial facility.

Health care providers, including hospitals and institutions, that provide routine patient care services that are approved for coverage cannot bill the insurer, HMO, or insured for any (1) services or costs that do not meet the definition of routine patient care services or (2) product or service for which the clinical trial sponsor is paying.

### ***Payment to Out-of-Network Providers***

An insurer or HMO must pay out-of-network providers the lesser of (1) the lowest contracted daily fee schedule or case rate it pays its Connecticut in-network providers for similar services or (2) billed charges. Out-of-network providers are prohibited from collecting more than the total of the amount paid by the insurer or HMO and the insured's deductible and copayment.

### ***Coverage Request Form***

The bill requires the Insurance Department to develop a standardized form that all providers must submit to the insurer or HMO when seeking to enroll an insured patient in a Parkinson's disease or MS clinical trial. The department must develop the form in consultation with:

1. at least one state nonprofit Parkinson's disease advocacy organization,
2. at least one state nonprofit MS disease advocacy organization,
3. at least one national nonprofit Parkinson's disease research or advocacy organization,
4. at least one national nonprofit MS research or advocacy organization,

5. the Connecticut Association of Health Plans, and
6. Anthem Blue Cross of Connecticut.

An insurer or HMO must use the department's form unless it is exempt from the bill and has the department's approval to use another form.

An insurer or HMO that receives a completed form from a provider requesting coverage for clinical trial routine patient care costs must approve or deny the request within five business days or, if using independent experts to review clinical trial requests, 10 business days. By law, requests for coverage of Phase III clinical trials must be approved or denied within 14 business days.

Under existing law, the Insurance Department has to (1) develop a form for use with cancer clinical trials and (2) adopt regulations to implement the coverage request form requirements.

### ***Exemption from Requirements***

Insurers and HMOs must submit their coverage policies for clinical trials to the Insurance Department for evaluation and approval. The department must certify whether the coverage policy is substantially equivalent to the bill's requirements. If it is, the insurer or HMO is exempt from the bill's requirements.

An exempt insurer or HMO must report annually in writing to the department that there have been no changes to the coverage policy. If there have been changes, the insurer or HMO must resubmit the policy for the department's certification.

### **OFF-LABEL DRUGS**

By law, individual and group health insurance policies that cover a prescription drug that is FDA approved to treat a certain type of cancer must also cover the drug when it is used for another type of cancer if it is recognized as a cancer treatment in one of three sources (known as "off-label drugs").

The bill also requires off-label drug use for FDA-approved drugs to treat Parkinson's disease or MS. The drug must be recognized for the treatment of Parkinson's disease or MS in the:

1. U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional,
2. American Medical Association's Drug Evaluations, or
3. American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information.

The bill specifies that it does not require coverage for experimental or investigational drugs or any drug that the FDA has determined to be contraindicated for the treatment of Parkinson's disease or MS. This is already law with respect to cancer drugs.

#### **COMMITTEE ACTION**

Insurance and Real Estate Committee

Joint Favorable Substitute

Yea    13        Nay   6        (03/16/2010)